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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.								
10/675,936	09/30/2003	F. William Studier	BSA 02-29	2367								
7590 Margaret C. Bogosian, Esq. Brookhaven Science Associates, LLC Building 375D P.O. Box 5000 Upton, NY 11973-5000		05/03/2007	<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">VOGEL, NANCY S</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td colspan="2">1636</td></tr></table>		EXAMINER		VOGEL, NANCY S		ART UNIT	PAPER NUMBER	1636	
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		MAIL DATE	DELIVERY MODE									
		05/03/2007	PAPER									

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/675,936	STUDIER, F. WILLIAM	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 April 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 53-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 53-60 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

Claims 53-60 are pending in the case.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/26/07 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The application discloses strains that are encompassed by the definitions for **biological material** set forth in 37 C.F.R. 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. 1.801-1.809, in the form of a declaration of applicant's representative must provide a statement. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession)

number, date of deposit, name and address of the depository, and the complete taxonomic description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54-56, 58-60 are vague and indefinite in the recitation of "T7 expression system host cells" since it is not clear what is intended by this phrase. Although T7 expression systems, in which the T7 RNA polymerase is used for the expression of a gene of interest which is under the control of a promoter recognized by T7 RNA polymerase, are generally known in the art, the specification does not define exactly what is intended by "T7 expression system host cells". For instance, it is not known whether said host cells are intended to comprise a gene of interest under the control of a T7 promoter, and/or whether a T7 RNA polymerase encoding gene is present, etc.

Claim 57 is vague and indefinite in the recitation of "derivatives thereof" since the term "derivative" is non-specific and relative in nature for which Applicant provides no definition. It provides no clarity as to what Applicant's claimed invention includes and what it does not include. Without a more specific definition, it is impossible to determine what and how many derivations comprise the invention. The nature and number of the derivations to arrive at the invention Applicant seeks to protect with the patent are not established such that a person skilled in the art would be apprised of the metes and

bounds of the claims. The limits of the inventions cannot be discerned and others could not know if they were infringing Applicant's claim.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 40 of copending Application No. 11/741,048, in view of Studier et al. (J. Mol. Biol, 1986, 189, 113-130) (cited by applicants) or Studier et al. (Meth. Enzymology, 1990, 185, 60-89) (cited by applicants). . Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the conflicting patent recite that transcription is under the control of a promoter whose activity can be induced by an exogenous inducer whose ability to induce said promoter is dependent on the metabolic

state of said bacterial cells, while the instant claims recite that the promoter is lac or lacUV5 promoter, or a T7 expression system. However, it would have been obvious to one of ordinary skill in the art to have used the well known lac or lacUV5 promoter, or a T7 expression system, since such expression systems are well known in the art, as taught by Studier et al. (J. Mol. Biol, 1986, 189, 113-130) (cited by applicants) or Studier et al. (Meth. Enzymology, 1990, 185, 60-89) (cited by applicants). One would have been motivated to do so by the well known ability to control such promoters.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 53-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 28 of copending Application No. 11/741,282 in view of Studier et al. (J. Mol. Biol, 1986, 189, 113-130) (cited by applicants) or Studier et al. (Meth. Enzymology, 1990, 185, 60-89) (cited by applicants). . Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the conflicting patent recite that transcription is under the control of a promoter whose activity can be induced by an exogenous inducer whose ability to induce said promoter is dependent on the metabolic state of said bacterial cells, while the instant claims recite that the promoter is lac or lacUV5 promoter, or a T7 expression system. However, it would have been obvious to one of ordinary skill in the art to have used the well known lac or lacUV5 promoter, or a T7 expression system, since such expression systems are well known in the art, as taught by Studier et al. (J. Mol. Biol, 1986, 189, 113-130) (cited by applicants) or Studier

et al. (Meth. Enzymology, 1990, 185, 60-89) (cited by applicants). One would have been motivated to do so by the well known ability to control such promoters.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1636

NV

4/30/07

  
NANCY VOGEL  
PRIMARY EXAMINER